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PCT/NZ2004/000146

RECD 16 AUG 2004
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CERTIFICATE

This certificate is issued in support of an application for Patent registration in a country outside New Zealand pursuant to the Patents Act 1953 and the Regulations thereunder.

I hereby certify that annexed is a true copy of the Provisional Specification as filed on 16 July 2003 with an application for Letters Patent number 527025 made by David Peter SHAW.

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Dated 2 August 2004.

Neville Harris
Commissioner of Patents, Trade Marks and Designs

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527025

Patents Form No. 4

Patents Act 1953

PROVISIONAL SPECIFICATION

PROSTHETIC VALVES FOR MEDICAL APPLICATION

I, David Peter SHAW, of Cossars Road, Tai Tapu, R.D. 2, Christchurch, New Zealand, a New Zealand citizen, do hereby declare this invention to be described in the following statement:

Title: Prosthetic Valves for Medical Application

Technical Field

The present invention relates to prosthetic valves for medical application. The valve of the present invention has been developed with special reference to a prosthetic heart valve, and therefore will be described with particular reference to this application. However, it will be appreciated that the valve of the present invention also could be used in other medical applications.

Background Art

Prosthetic heart valves are used to replace a patient's own defective or damaged valves. Prosthetic heart valves currently in use are divided into two broad categories:- tissue valves and mechanical valves.

Tissue valves are either naturally-formed valves taken from pig hearts or valves formed from pericardium tissue taken from bovine hearts. In general, tissue valves are well accepted by the patient's body and require only the minimum anticoagulation treatment. However, tissue valves have the drawback that they wear out relatively rapidly, with a life of between 10 and 20 years.

Mechanical valves have excellent durability:- accelerated testing suggests that mechanical valves may have a life of the order of 200 years. However, mechanical valves have the drawback that they are not readily accepted by a patient's body and require long-term anticoagulation treatment to prevent thromboembolic complications. This is undesirable from the point of view of the patient's general health.

It is therefore an object of the present invention to provide a prosthetic valve, more particularly a heart valve, which has the durability of a mechanical valve but which is as compatible with the patient's body as a tissue valve, and thus requires no, or minimal, anticoagulation therapy.

Disclosure of Invention

The present invention provides a prosthetic valve in the form of a flap valve which includes at least three complimentary flaps arranged to allow movement of liquid through the valve only in one direction, each flap valve being made of a flexible openwork structure of a medically acceptable metal wire.

Brief Description of Drawings

By way of example only, a preferred embodiment of the present invention is described in detail, with reference to the accompanying drawings in which:-

Figure 1 is a plan view of a prosthetic heart valve in accordance with the present invention;

Figure 2 is a view of the valve of Figure 1 from below;

Figure 3 is a side view taken along the line of Arrow III of the valve of Figure 1; and

Figure 4 is a side view taken along the line of Arrow IV of the valve of Figure 1.

Best Mode for Carrying out the Invention

Referring to the drawings, a prosthetic aortic valve 2 is basically similar in construction to a tissue valve, i.e. it is a flap valve which consists of three equal size flaps 3,4,5 of

substantially planar material, each flap being formed, in plan, as slightly larger than one-third of a segment of a circle.

Thus, the flaps 3,4,5 can move apart to allow fluid to pass through the valve in the direction of Arrow A (Figure 3), but the overlap of adjacent flaps closes the valve in the reverse direction.

Each flap 3,4,5 is made of a flexible openwork structure of a medically acceptable metal wire. As used herein, the term "medically acceptable" means a metal which is non-toxic to the body and preferably which is inert in the body, i.e. it does not provoke a "foreign body" reaction when implanted in the body. It is envisaged that the valve of the present invention would have the flaps 3,4,5 made from titanium wire or a medically approved titanium alloy wire (for example the nickel/titanium Nitenol (trademark) alloys), but other medically acceptable metals could be used providing they can be drawn as fine flexible wires.

It is envisaged that a flexible openwork structure would be made from the wire, e.g. by using a knitting type of process or by manufacturing chain mail (i.e. a series of separate, interlocked rings of wire), but a weaving type of process might also be suitable. The finished openwork structure must be able to flex without permanently bending.

Woven flaps would provide a relatively stiff structure, whereas the chain mail structure would provide a very flexible flap; the stiffness of a knitted structure is midway between that of the woven structure and that of the chain mail structure.

Titanium and titanium alloy wires are favoured because they are known to be not only

inert when implanted in the body but also to promote good tissue growth. Further, evidence from titanium implants used in other areas (e.g. the mouth) suggests that infections can be cleared from a titanium surface more easily than from other foreign materials.

Each flap 3,4,5 has a curved outer edge 3a, 4a, 5a, from each end of which a side edge 6/7, 8/9, 10/11 extends inwards to meet the adjacent side edge as an acute angle, but with the apex between the side edges curved.

As shown in Figures 3 and 4, the outer edges 3a, 4a, 5a of each flap are curved in the side view, with the side edges 6/7, 8/9, 10/11 raised relative to the midpoint of the outer edges. This increases the overlap between adjacent flaps where the adjacent side edges 6/8, 9/10 and 7/11 of the adjacent flaps overlap, and thus greatly reduces any risk of reverse flow through the valve (i.e. in the direction opposite to Arrow A).

The valve shown in the drawings is a semi-stented design, i.e. with a degree of reinforcing around the periphery of the valve, formed by a peripheral rib 13 which may simply be a thickened and/or reinforced area. The rib 13 is omitted from the views shown in Figures 3 and 4, for reasons of clarity.

The valve also may be produced as a fully stented valve, i.e. with the three flaps 3,4,5 mounted on a rigid annulus. Another possibility is to omit peripheral reinforcing altogether and produce the valve as a completely stentless valve; a stentless design is advantageous for percutaneous insertion.

It is envisaged that the above described valve would be implanted in a patient with an initial coating over the flaps 3,4,5 of a degradable sealing material which would

prevent leakage through the openwork structure of the flaps until such time as the patient's own system had developed its own coating over the flaps, by endothelisation.

Fig. 1

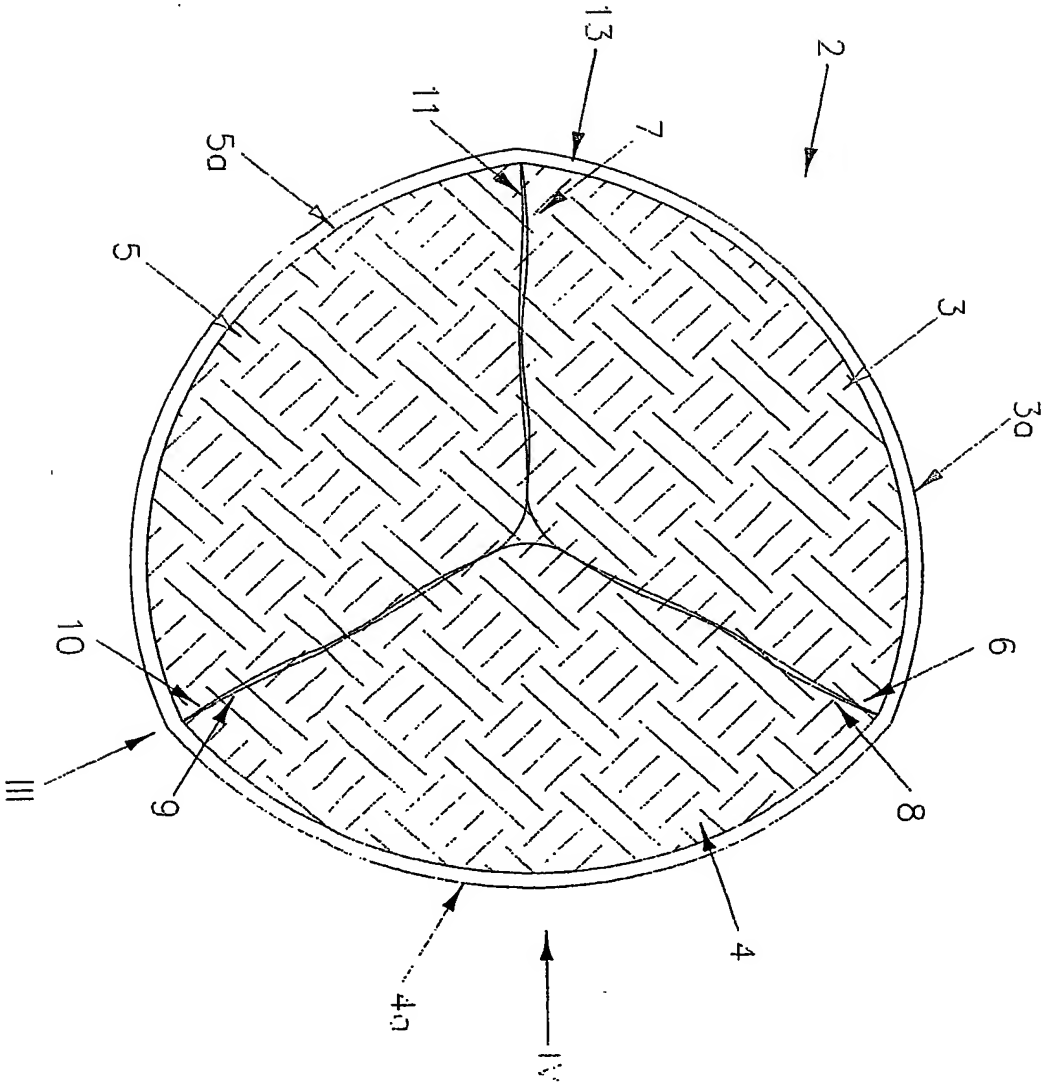

FIG. 1

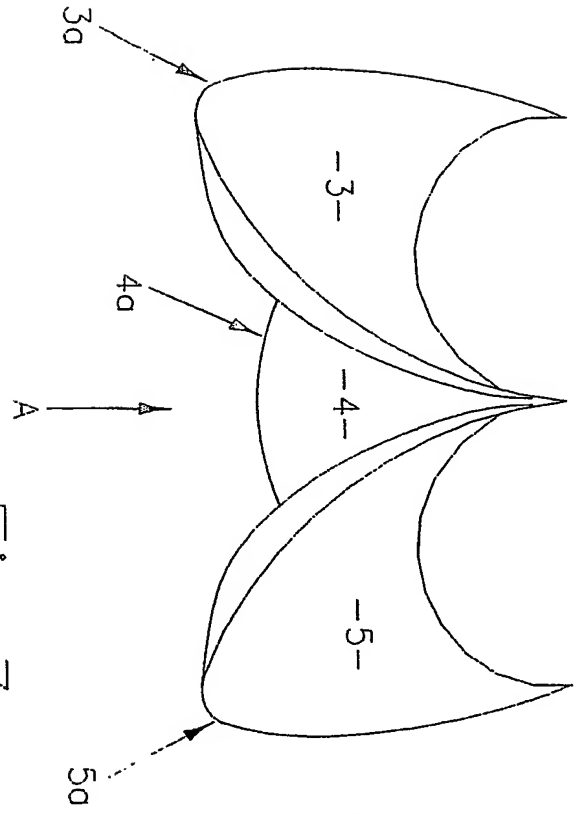

Fig. 3

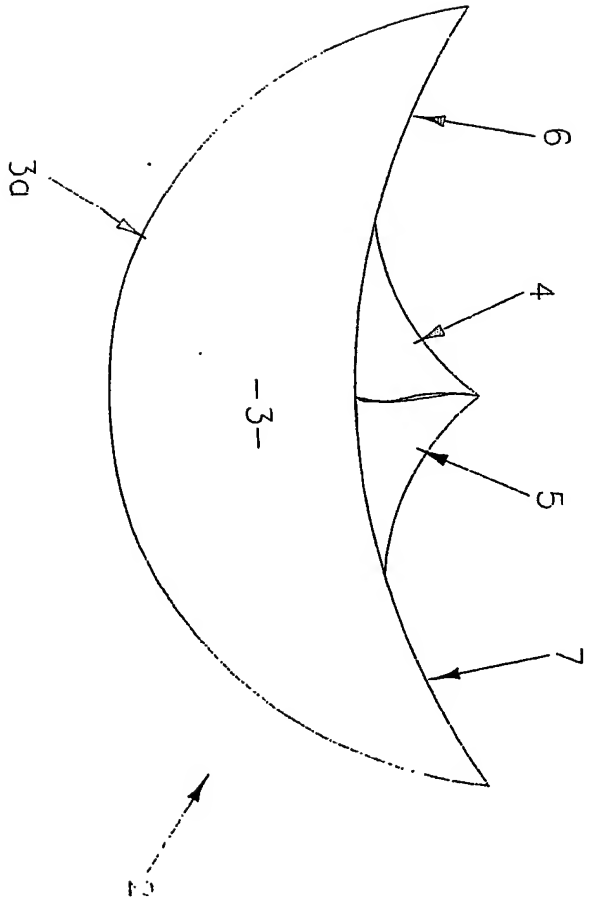

Fig. 4